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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,471	07/27/2001	Leland F. Wilson	9050-0053	3484

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REED & ASSOCIATES
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EXAMINER

STILLER, KARL J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/05/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/919,471	Wilson et al.
	Examiner Karl Stiller	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-45, and 50, drawn to a method of enhancing sexual desire and responsiveness in a female, comprising orally administering an effective amount of an orally active androgenic agent with or without a lipoidal carrier or with or without additionally administering at least one additional active agent, diversely classified in Class 514, for example, Subclasses 169, 171, 178, 247, etc.
- II. Claim 46, drawn to a method of maintaining (or) improving the tissue health of female genitalia, comprising orally administering to a female an effective amount of an orally active androgenic agent, diversely classified in Class 514, for example, Subclasses 169, 171, 178, 247, etc.
- III. Claim 47, drawn to a method of preventing vaginal atrophy, comprising orally administering to a female an effective amount of an orally active androgenic agent, diversely classified in Class 514, for example, Subclasses 169, 171, 178, 247, etc.
- IV. Claim 48, drawn to a method of preventing vaginal pain during intercourse, comprising orally administering to a female an effective amount of an orally active androgenic agent, diversely classified in Class 514, for example, Subclasses 178, 247, 254.06, 611, etc.

- V. Claim 49, drawn to a method for alleviating vaginal itching and dryness, comprising orally administering an effective amount of an orally active androgenic agent, diversely classified in Class 514, for example, Subclasses 178, 247, 254.06, 611, etc.
- VI. Claims 51-54, drawn to an oral dosage form or kit, comprising from about 1 microgram to 150 mg testosterone propionate and a pharmaceutically acceptable carrier, diversely classified in Class 514, for example, Subclasses 178, 247, 254.06, 611, etc.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, VI; and II, III, IV, V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group I is a method which functions to enhance sexual desire and responsiveness in a female, comprising administering an orally active androgenic agent with or without a lipoidal carrier or with or without the additional administration of at least one additional active agent. The invention of Group II is a method which functions to maintain (or) improve the tissue health of female genitalia, comprising the administration of an androgenic agent, alone. The invention of Group III is a method which functions to prevent vaginal atrophy, comprising the administration of an androgenic agent, alone. The invention of Group IV is a method which functions to prevent vaginal pain during intercourse, comprising the administration of an androgenic agent, alone. The invention

of Group V is a method which functions to alleviate vaginal itching and dryness, comprising the administration of an androgenic agent, alone. The invention of Group VI is an oral dosage form or kit comprising an orally active androgenic agent and a pharmaceutically acceptable carrier.

Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for using the product as claimed can be used in a materially different process, such as in a method to promote muscle growth in a male patient.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: orally active androgenic agents, and additional active agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species which is a single disclosed orally active androgenic agent (e.g., testosterone decanoate, dihydrotestosterone propionate, dehydroepiandrosterone, etc.) with or without a single disclosed additional active agent (e.g., misoprostol, minoxidil, nitroglycerin, trazodone,

etc.) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-14, 16-17, 19-53 are generic.

The search for all species of individual agents useful in the method and products herein presents an undue burden on the office due to their structural dissimilarities and correspondingly diverse classification. Note that the search is not limited to the patent files nor restricted to the classification of the actives useful herein. For example, dihydrotestosterone propionate is classified in Class 514, Subclass 178; minoxidil is classified in Class 514, Subclass 247; nitroglycerin is classified in Class 514, Subclass 611; trazodone is classified in Class 514, Subclass 254.06.

Therefore, due to the structural diversity of active compounds useful herein and their corresponding diverse classification, the search for all species of combinations would present an undue burden on the office.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction and specie election is considered complex, a call to the attorney for a telephonic election was not made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone

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number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
November 29, 2001

Minna Moezie
MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600